Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

M-2, Part VI
Chapter 12

March 14, 1994

1. Transmitted is a revision to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Programs," Part VI, "Pathology and Laboratory Medicine Service," Chapter 12, "Personnel," formerly entitled "Electron Microscopy in Laboratory Services." Brackets have not been used to identify changes in text.

2. Principal changes are:

a. Paragraph 12.02: Defines Pathology and Laboratory Medicine Service personnel policy.

b. Paragraph 12.03: Defines the requirements for credentialing and/or privileging of physicians.

c. Paragraph 12.04: Defines the qualifications and responsibilities of laboratory managers.

d. Paragraph 12.05: Defines the qualifications and responsibilities of section supervisors.

e. Paragraph 12.06: Defines the qualifications and responsibilities of testing personnel.

f. Paragraph 12.07: Defines the qualifications and responsibilities of other laboratory personnel.

g. Paragraph 12.08: Defines requirements for testing sites outside Pathology and Laboratory Medicine Service.

3. Filing Instructions

Remove page	Insert pages
49 through 52	12-i through 12-ii
	12-1 through 12-17

4. RESCISSIONS: M-2, Part VI, Chapter 12, change 69, dated January 3, 1986; Interim Issue 10-81-58; and VHA Circular 10-81-059.

~~S/3/14/94 by Dennis Smith for~~
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Distribution: RPC: 1283 is assigned
FD

Printing Date: 3/94

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RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part VI, Chapter 12, change 69, dated January 3, 1986

2. Interim Issues

II 10-81-58

3. VHA Circulars

10-76-124
10-81-059

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CHAPTER 12. PERSONNEL

12.01 PURPOSE

This purpose of this chapter is to establish policy for qualifications and responsibilities of Pathology and Laboratory Medicine Service personnel.

12.02 POLICY

a. Pathology and Laboratory Medicine Services within the Department of Veterans Affairs (VA) medical centers are to be staffed by a sufficient number of qualified laboratory testing personnel and supportive staff to perform required tests promptly and proficiently.

b. Only procedures and tests which fall within the scope of the education, training, and experience will be performed by the staff employed to perform and supervise technical procedures in the laboratory. Work assignments in each laboratory section must be consistent with the qualifications of employees.

c. Continuing Education. Pathology and Laboratory Medicine Service must provide, or make available, continuing education to ensure the continued proficiency and competency of personnel. Educational programs include, but are not limited to, technical, scientific, quality assessment and improvement, safety, and administrative issues that meet the needs of the personnel.

(1) The Continuing Educational Programs are based, at least in part, on the findings of the monitoring and evaluation of the quality of laboratory services provided (see Ch. 2).

(2) Continuing Education Programs are held at intervals defined by the laboratory, but at least quarterly.

(3) Technical personnel on all work shifts participate and document program content and attendance of at least 10 hours of educational activities each year. The opportunity to attend outside workshops, institutes, and local, regional, or national society meetings is provided for (at least) supervisory personnel, depending on resource availability.

c. An orientation program is provided for each new technical staff member.

d. Before test procedures are independently performed Competency of all personnel is documented and reported and thereafter on an annual basis.

e. Documentation includes:

(1) Orientation and annual refresher training for such topics as equipment and utility management systems,

(2) Infection control practices,

(3) Chemical hygiene,

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(4) Radiation safety,

(5) Fire and general safety, and

(6) Disaster plans.

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12.03 QUALIFICATIONS AND RESPONSIBILITIES FOR PHYSICIANS IN PATHOLOGY AND LABORATORY MEDICINE SERVICE

Physicians are to be credentialed and privileged at the time of their initial appointment and periodically thereafter. Credentialing procedures are outlined in the Medical Staff Bylaws of the medical center.

12.04 QUALIFICATIONS AND RESPONSIBILITIES FOR LABORATORY MANAGERS

a. Education and experience requirements for the Laboratory Manager vary significantly based on laboratory setting and size. At a minimum, the Laboratory Manager will meet the requirements for the Clinical Laboratory Supervisor (see par. 12.05).

b. The Laboratory Manager must also have demonstrated supervisory and administrative abilities and meet the credentials required by the College of American Pathologists (CAP) for Section Supervisor.

c. One year of experience must have been at a level of difficulty comparable to that of the next lower grade level in the occupational series. NOTE: The qualification standard for "Supervisory Positions in General Schedule Occupations," in part III of Handbook X-118 should be used in conjunction with the other requirements of the position.

d. The Laboratory Manager occupies a staff position and participates with the Chief, Pathology and Laboratory Medicine Service, in planning policies, adopting procedures, and resolving problems that affect the entire Laboratory unit. The scope of duties and responsibilities for the Laboratory Manager include:

(1) Administrative oversight of the Laboratory in such areas as:

(a) Safety,

(b) Budget,

(c) Personnel relations,

(d) Inventory control, and

(e) Materials management.

(2) Technical oversight in such areas as:

(a) Research and development,

(b) Quality control,

(c) Quality assurance,

(d) Regulatory compliance,

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(e) Technical education,

(f) Equipment selection,

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(g) Evaluation,

(h) Maintenance,

(i) Methodologic procedure review,

(j) Ancillary testing, and

(k) Referral testing.

e. The following list of Laboratory Manager duties is intended to serve as a template for use in medical centers:

(1) Large laboratories may delegate these responsibilities to many different individuals or have specific technologist positions in such areas as quality improvement, education, and safety (see par. 12.07).

(2) In smaller laboratories, the Laboratory Manager may perform these duties and those of the Laboratory Section Supervisor and testing personnel.

(3) The Laboratory Manager's responsibilities are to:

(a) Advise the Chief, Pathology and Laboratory Medicine Service, and other management officials on the problems of the unit and their impact.

(b) Carry out duties involving recruitment and hiring of laboratory personnel.

(c) Ensure qualified staff coverage for laboratory operation, including providing orientation and training.

(d) Review and approve performance ratings and recommend promotions, demotions, or dismissals.

(e) Hear group grievances and serious employee complaints and disciplinary cases not resolved at a lower level.

(f) Recommend and implement the laboratory budget and approve laboratory expenditures.

(g) Evaluate, select, and prepare justifications for major expenditures and needs of the service.

(h) Establish and maintain quality control and quality assurance programs for each laboratory section.

(i) Provide oversight and direction for the laboratory's computer system.

(j) Establish and maintain an on-going continuing education program for all levels of laboratory personnel.

(k) Assist and participate in educational programs affiliated with institutions providing training for individuals in Laboratory or other related medical fields of study.

(l) Ensure adequate safety measures and procedures in the Laboratory.

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(m) Make recommendations for the overall laboratory physical facility, including design, development, and modification of existing and new facilities.

(n) Evaluate programs and plan for changes and improved methods.

(o) Participate in long-range planning for the service in such areas as:

1. Personnel requirements,

2. Space needs, and

3. New procedures for replacement or addition to the testing menu.

(p) Make recommendations on resources available for projects, the timing of initiating, dropping, or curtailing particular activities, and the need for change.

(q) Ensure compliance with requirements of accreditation agencies.

(r) Serve as the laboratory liaison to services and committees in the medical center.

(s) Solve inter-departmental problems and facilitate communications.

(t) Serve as the liaison for contacts from outside the medical center.

12.05 QUALIFICATIONS AND RESPONSIBILITIES FOR SECTION SUPERVISORS

a. Section Supervisors. All VA Section Supervisors must have education, training and professional experience in recent technology and procedures. The individuals must have demonstrated in their work experience and training that they possess or have the potential to develop the qualities essential for supervision. The Section Supervisor must:

(1) Provide day-to-day supervision or oversight of the section's operation, testing personnel, and reporting of test results.

(2) Be accessible and provide day-to-day supervision of test performance, consultation, and resolution of technical problems.

(3) Provide direct supervision when testing is performed by any individual who has less than an Associate Degree.

(4) Monitor test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

(5) Ensure that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

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(6) Ensure that patient test results are not reported until all corrective actions have been taken, and the test system is verified to be properly functioning.

(7) Advise higher supervisory and management officials on problems involving the relationship and impact of the work of the section to broader programs.

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(8) Oversee personnel activities within the section as:

(a) Providing administrative and technical orientation for all testing personnel;

(b) Identifying and providing for developmental, training, and continuing education needs of employees; and

(c) Evaluating and documenting, annually, the performance and competency of all testing personnel.

b. Clinical Laboratory Section Supervisor. The Clinical Laboratory Section Supervisor must have work experience, education and training of a professional quality and scope sufficient to perform functions at the grade level for which being considered, and meet the supervisory credentials required by CAP.

c. Histology Supervisor. The Chief, Pathology and Laboratory Medicine Service, may appoint a Histology Supervisor, who is responsible for the day-to-day supervision or oversight for all histologic activities which precede the interpretation of slides and other materials by pathologist:

(1) Applicants selected to be Histology Supervisors must:

(a) Qualify under the appropriate VA personnel qualification standard and must have had at least 4 years of full-time experience as a Histotechnologist.

(b) Have education, training and professional experience in recent technology and procedures in histology, and

(c) Demonstrated in their work experience and training that they possess or have the potential to develop the qualities essential for supervision. NOTE: The responsibilities for this individual are similar to those of the clinical laboratory section supervisor.

d. Cytology Supervisor. The Chief, Pathology and Laboratory Medicine Service, may appoint a Cytology Supervisor for the day-to-day supervision or oversight of activities in the area.

(1) Cytology Supervisors applicants must:

(2) Meet the appropriate VA personnel qualification standard and must have had at least 4 years of full-time experience as a Cytotechnologist.

(a) Have education, training and professional experience in recent technology and procedures in cytology, and

(b) Demonstrate in their work experience and training that they possess or have the potential to develop the qualities essential for supervision.

(3) In addition to responsibilities similar to those of the Clinical Laboratory Supervisor, the Cytology Supervisor applicant must ensure all

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cytology cases and reviews are documented according to specified quality assurance procedures as outlined in Chapter 6.

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12.06 QUALIFICATIONS AND RESPONSIBILITIES FOR TESTING PERSONNEL

NOTE: The American Society of Clinical Pathologists, "Scope of Duties/Responsibilities for Technician and Technologist Levels of Medical Laboratory Personnel," memorandum dated April 21, 1992, was used as a reference.

The scope of duties and responsibilities for testing personnel is divided into two categories which encompass all technician and technologist levels of VA Medical Laboratory testing personnel.

a. Technician. The technician category includes all Histotechnicians and Medical Technicians. Technician qualifications and responsibilities follow:

(1) A technician applicant must have the appropriate educational background to meet VA personnel qualification standards and to perform laboratory tests or procedures according to established and approved protocols. These tests or procedures are performed directly under the supervision of a qualified technologist, supervisor, or Chief, Pathology and Laboratory Medicine Service, or designee.

(2) The technician may perform Laboratory procedures in more than one of the major areas of the laboratory, or concentrate activity in one area such as immunohematology (blood banking), chemistry, hematology, immunology, microbiology, or histology.

(3) The technician's duties performed under the direction of a qualified supervisor are to:

(a) Follow established procedures for collecting and processing biological specimens for analysis.

(b) Perform assigned analytical tests or procedures which require less independent judgment than at the technologist level.

(c) Recognize factors that affect measurements and results and take appropriate action according to predetermined protocols.

(d) Recognize abnormal results and refer them to designated supervisory personnel.

(e) Operate instruments within the scope of training, utilizing established protocols and quality control checks .

(f) Recognize equipment malfunctions and notify appropriate supervisory personnel.

(g) Communicate information such as test results, normal range, and specimen requirements to authorized sources.

(h) Perform routine quality control practices and maintain accurate records.

(i) Recognize out-of-control results and notify supervisory personnel.

(j) Demonstrate Laboratory technical skills to new employees and students.

(k) Actively participate in continuing education programs.

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b. Technologist. The technologist category includes all Cytotechnologists, Histotechnologists, and Medical Technologists. Technologist qualifications and responsibilities follow:

(1) A technologist must have the appropriate educational background to meet the VA personnel qualification standards.

(a) A technologist performs laboratory procedures, which require the broad exercise of independent judgment and responsibility with minimal technical supervision.

(b) The technologist maintains and documents the optimal functioning of Laboratory equipment, performs and documents quality assurance activities related to test performance, and may function as a supervisor, educator, manager, or researcher within a Medical Laboratory setting.

(c) The term "technologist" includes individuals who perform a broad-range of laboratory procedures as well as those who concentrate their activities in an area such as:

1. Immunohematology (blood banking),

2. Chemistry,

3. Hematology,

4. Immunology,

5. Microbiology,

6. Histology, or

7. Cytology.

(2) The technologist reports to a supervisor or the Chief, Pathology and Laboratory Medicine Service, or designee (see Ch. 1). The technologist has an understanding of roles and relationships of practitioners in the health-related fields. The technologist's role subsumes all aspects of the technician's role. The technologist's duties performed in collaboration with a supervisor are to:

(a) Evaluate and solve problems related to collection and processing of biological specimens for analysis.

(b) Perform complex laboratory procedures; recognize deviation from expected results; analyze and correct problems using scientific principles.

(c) Analyze quality control data, make judgments concerning the results, and take appropriate action to maintain accuracy and precision.

(d) Answer inquiries regarding test results, methodology, test specificity and sensitivity, and specific factors which influence test results.

(e) Participate in the evaluation of new techniques and procedures in the laboratory in terms of:

1. Personnel,

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2. Equipment,

3. Space,

4. Method comparison,

5. Cost analysis, and

6. Establishment of reference intervals.

(f) Write and revise technical procedures.

(g) Incorporate principles of educational methodology in the instruction of new employees and students and in the Laboratory's inservice and Continuing Education Program.

(h) Give direction and guidance to Medical Laboratory technicians and support personnel.

(i) Develop and direct special projects and studies.

(j) Actively participate in Continuing Education Programs.

c. Testing personnel may include doctoral and non-doctoral chemists and Microbiologists, who meet VA qualification standards. These individuals are qualified to perform testing in their respective subject matter areas. Their responsibilities are similar to those of the technologist (see Ch. 2).

d. Opportunities for employment and advancement of military trained personnel in VA medical center Laboratories are outlined in the qualification standards for Clinical Laboratory experience gained in the military (after advanced military training is completed) is considered acceptable experience.

e. Currently practicing VA medical center testing personnel, who do not have an associate degree or equivalent, must be reviewed annually for competent performance by a Laboratory supervisor for each test performed. All newly-hired testing personnel must meet the minimum qualification standards for their positions.

f. All medical technicians, including military trained medical technicians, may compete for Medical Technologist positions through appropriate experience and completion of educational requirements financed by tuition support and/or other assistance programs.

12.07 OTHER LABORATORY PERSONNEL AND ADDITIONAL ASSIGNMENTS

The Clinical Laboratory requires a variety of clerical and technical support personnel, such as phlebotomists, specimen processors, computer data entry clerks, file clerks, secretaries, receptionists, and supply, billing and inventory clerks. There are additional assignments which require professional knowledge and expertise in laboratory medicine such as Clinical Chemist, microbiologist, computer coordinator, instructor, safety officer, quality

assurance/control specialist, and technical consultant. The variety of tasks assigned to these positions may vary from one lab to the next, but are commonly included in the functional categories described as follows: NOTE: These descriptions should be taken as representative of the division of labor in a typical

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laboratory, and not as a mandatory blueprint. Each laboratory may divide the tasks and functions among the available personnel as is appropriate for local policy, convention, and work flow expediency.

a. Clerical Personnel

(1) Clerical personnel are responsible for:

(a) Routine office work as:

1. Filing laboratory test request slips and reports,

2. Answering telephones,

3. Transcribing test request orders from requisitions into the computer,

4. Accessioning patient samples in the laboratory, and

5. Collecting and collating workload data;

(b) Preparing data for routine and special reports;

(c) Maintaining inventories of clerical and laboratory supplies;

(d) Tracking invoices for supplies and fee basis testing; and

(e) Interacting with patients, nurses and physicians, as well as laboratory coworkers.

(2) The personnel performing these duties are often hired in the clerk/typist, medical clerk, or program assistant job series.

b. Typist and/or Word Processing Clerk

(1) The typist and/or word processing clerk is responsible for:

(a) Transcribing, typing and assembling the many laboratory manuals, procedures, protocols, and policies, keeping them current with changing regulations and standards as determined by laboratory supervisors, managers, and directors;

(b) Preparing the minutes of meetings and correspondence according to the formats required by various governing and accrediting agencies and committees;

(c) Typing preliminary and final narrative laboratory reports, such as autopsy, bone marrow, and tissue biopsy reports, for inclusion in patients' permanent records; and

(2) Functions that are typically performed by clerk/typists, secretaries, program assistants, or office automation assistants and clerks.

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c. Phlebotomist. The training of a phlebotomist encompasses the techniques for obtaining blood specimens using syringes, vacutainers, and finger stick procedures; and includes a thorough understanding of sample stability and the purpose of the various separators, preservatives, and anticoagulants in blood collection tubes. The phlebotomist is responsible for:

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(a) Collecting blood specimens from hospitalized patients as well as from outpatients in a central lab blood/drawing room, remote blood/drawing room, or even the patient's home.

(b) Interacting with the hospital computer system to generate blood/drawing lists, verify sample collections, and document collection failures.

NOTE: Functions that are typically performed by health technicians or medical laboratory aides under the supervision of a technologist or technician.

d. Technical Support Personnel. Technical support personnel are responsible for:

(a) Evaluating the integrity of patient samples prior to testing, preparing aliquots of the samples as required by individual lab protocols, and ensuring sample identification is reliably maintained; and

(b) Processing the samples for testing. Specimen processing may include preparation and staining of tissue and cytologic material, preparation of fluids and tissues for microbial culture, centrifugation of blood, urine, and body fluid samples, measurement of urine and fluid sample volumes, refrigerating, freezing, or preserving samples with chemical agents as appropriate, and packaging samples for delivery to remote laboratories. NOTE: Assisting at autopsy is part of this category.

NOTE: Technical support personnel are usually health technicians, medical laboratory aides, or pathology technicians working under the supervision of a technologist or technician.

e. Technical Specialists

(1) Clinical Chemist. Clinical chemistry sections in VA medical center laboratories classified as very large (VL), large (L) or medium (M) may be under the technical supervision of a Clinical Chemist (par. 1.05). The chemist may be the laboratory technical authority in clinical chemistry, immunoassay, or toxicology providing technical advice on unprecedented or complex problems to technologists, other chemists, and physicians.

(a) The Clinical Chemist must have professional training and experience equivalent to the college training required for at least a Bachelor's Degree, with specified minimum credits in chemistry courses, at the master's or doctoral level in a laboratory science.

(b) The Clinical Chemist has in-depth, professional knowledge of chemical principles, theories, practices, and established methodologies sufficient to perform thefull-range of duties involved in developing and modifying methods that are used to analyze body fluids and tissues.

(c) The duties of the chemist commonly include:

1. Evaluating needs for new chemistry tests, new methods for existing tests, and new analytical instrumentation and equipment.

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2. Modifying or developing analytical testing methods to provide new clinical information about a wide variety of conditions in health and disease.

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3. Training lower grade chemists, technologists, and technicians in methods new to the laboratory.

4. Training pathology residents in clinical chemistry theory and techniques.

5. Advising hospital staff on appropriateness of specific chemistry tests for the clinical context and the usefulness of the information that would be yielded.

6. Determining the cause of apparently inappropriate or unexpected test results.

7. Suggesting alternate testing strategies to overcome ambiguities in clinical diagnoses and to overcome the effect of physiological, pharmacological, or methodological interferences with standard testing methods.

8. Evaluating the quality and cost effectiveness of chemistry testing sent to outside specialty or reference labs, and setting technical criteria for reference laboratory contracts.

(2) Microbiologist. Clinical microbiology sections in VA medical center laboratories classified as very large (VL), large (L), or medium (M) may be under the technical direction of a clinical microbiologist. The Microbiologist may be the medical facility's laboratory technical authority on the characteristics and life processes of microorganisms and their relationship to humans in health and disease.

(a) The Microbiologist must have the professional training and experience equivalent to at least a bachelor's degree in a laboratory science, though most typically is at the master's or doctoral level. The expertise of this person encompasses a comprehensive knowledge of the pathogenically significant:

1. Protozoa,

2. Bacteria,

3. Fungi,

4. Rickettsiae,

5. Viruses,

6. Mycobacteria, and

7. Parasites.

(b) The breadth of knowledge required for this work includes microbial biochemistry, physiology, and taxonomy, serology, genetics, molecular biology, and cytology.

(c) The microbiologist routinely interacts and consults with the Hospital Infection Control Officer, hospital clinicians, and pharmacists regarding patterns and trends of antibiotic resistance and recommends cost effective strategies of antibiotic utilization;

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professional interactions are with laboratory technologists and technicians, physicians, infection control nurses, industrial hygienists, and city, county, state, and Federal Public Health agencies or bodies.

(d) Duties of the microbiologist commonly include:

1. Evaluating the need for new microbial identification procedures, and introducing them to the laboratory as is clinically necessary.

2. Modifying existing methods or identification criteria to stay current with changing taxonomy, antimicrobial drug resistance, or clinical relevance.

3. Providing training to lower grade microbiologists, technologists, and technicians in procedures new to the laboratory.

4. Training pathology residents and infectious disease personnel in clinical microbiology theory and techniques.

5. Advising hospital staff on appropriateness of specific microbiology tests for the clinical context and the usefulness of the information yielded.

6. Determining the cause of apparently inappropriate or unexpected test results.

7. Suggesting alternate testing strategies to overcome ambiguities in clinical diagnoses and to overcome the effect of physiological, pharmacological or methodological interferences with standard testing methods.

8. Evaluating the quality and cost effectiveness of microbiology testing sent to outside specialty or reference labs, and setting technical criteria for reference laboratory contracts.

f. Computer Coordinator

(1) The Computer Coordinator is responsible for ensuring the uninterrupted functioning of laboratory computer services. The position requires:

(a) A broad knowledge of the functioning of the laboratory, as well as comprehensive knowledge of the laboratory software in the VA Decentralized Hospital Computer Program (DHCP); and

(b) Interaction with all the departments of the laboratory, with other services throughout the hospital, and close cooperation with the medical center Information Resources Management Service (IRMS) computer services.

(2) The job may entail managing and troubleshooting free/standing or networked microcomputers.

(3) The Computer Coordinator position is typically filled by a technologist, chemist, or microbiologist with an aptitude for computers.

g. Instructor. The Instructor is responsible for scheduling and providing in-service education for the laboratory staff; and maintaining all required documentation for each individual in Pathology and Laboratory Medicine Service, which includes orientation checklists, and annual review of critical areas, e.g., blood borne disease, hazard communication, critical equipment and utility user training, fire and safety training.

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(1) The Instructor may interact with other services in the event that laboratory topics need to be communicated.

(2) The Instructor may direct or be affiliated with a formal laboratory training program, e.g., a medical technology program. Responsibilities may include:

(a) Scheduling training assignments,

(b) Developing the curriculum with other faculty members,

(c) Designing theoretical and practical examinations,

(d) Evaluating students' performance, and

(e) Advising management on policy and procedures for the efficient operation, development, and control of staff and resources.

(3) This position is typically filled by a senior level technologist with national certification and a graduate degree.

h. Safety Officer. The Safety Officer may serve as the Pathology and Laboratory Medicine Service representative to the Hospital Safety Committee, chairperson of the Pathology and Laboratory Medicine Service Subcommittee, and as the Chemical Hygiene Officer.

(1) The Safety Officer is responsible for ensuring the clinical laboratory adheres to all practices and regulations governing safety in the work place. These responsibilities include:

(a) Identifying and abating physical, chemical, electrical, and microbiological hazards that may exist in the laboratory;

(b) Documenting accidents and recommending procedures to prevent their recurrence; and

(c) Documenting that all employees are cognizant of current laboratory and hospital fire and safety policies.

(2) The laboratory Safety Officer monitors and documents work place and personnel radiation exposure, in accordance with NRC and hospital radiation safety guidelines. NOTE: Radiation safety issues in the clinical laboratory are the responsibility of the safety officer, but may be delegated to a knowledgeable technical specialist such as a medical technologist performing radioimmunoassay testing, or the clinical chemist. The duties include ensuring that phlebotomists and testing personnel observe universal precautions against biohazards in the work place, and that exposures to biohazards are appropriately documented and referred for treatment.

(3) The Safety Officer routinely interacts with personnel in all laboratory departments, and with medical center industrial hygienists, radiation safety

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officers, fire protection engineers, biomedical engineers, and infection control coordinators.

(4) The Safety Officer position is typically filled by a senior-level technologist, chemist, or microbiologist with national certification.

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i. Quality Improvement and/or Control Specialist. The Quality Improvement and/or Control Specialist is (are) responsible for quality control which requires a working knowledge of statistical techniques and their application in monitoring test performance in accordance with accreditation requirements.

(1) The Quality Improvement and/or Control Specialist must have a comprehensive knowledge of both the theory and practical aspects of the technology involved in testing. The position involves:

(a) Conducting test precision and accuracy studies;

(b) Verifying reference ranges by testing normal populations;

(c) Accumulating, collating, and statistically analyzing the results of the testing of control samples;

(d) Identifying and documenting test performance failure before patient care is affected; and

(e) Researching control and proficiency testing deficiencies.

(2) The Quality Improvement and/or Control Specialist interacts with supervisors and testing personnel in the laboratory, with representatives of test reagent and instrumentation manufacturers, and with organizations involved in inter-laboratory quality control and proficiency testing.

(3) Larger laboratories may have several quality control specialists, each having an area of expertise, such as chemistry, hematology, or microbiology.

(4) In smaller labs the general supervisor may perform these duties.

(5) The Quality Improvement and/or Control Specialist is typically a senior-level technologist, chemist, or microbiologist with national certification and a particular interest in quality improvement and statistical methods.

j. Technical Consultant. The role of the Technical Consultant encompasses a wide range of laboratory-related activities involving consultation with other clinical and administrative services in the medical center. Consultation is often provided in areas such as clinical pharmacology, infectious disease, testing procedures and requirements, waste disposal, chemical hazards, accreditation requirements, quality assurance activities, and laboratory design. NOTE: Specific consultative duties of the ancillary testing coordinator are discussed in chapter 12.

(1) The duties of the Technical Consultant may be incorporated in many laboratory positions, but it may also be a discrete position within the service.

(2) The minimal level for the Technical Consultant position is typically a senior technologist, chemist,or microbiologist with national certification.

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k. Lead Technologist. The Lead Technologist assists the section supervisor and may provide technical expertise to staff in a particular subject matter area. This position differs from the supervisor's position in that the lead technologist may resolve minor, informal problems from employees, or may refer problems to the supervisor.

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Consultation is often sought or provided in response to employee questions regarding procedures, policies, and directives, or to the supervisor in the lead technologist's area of expertise. This position differs from other technologist positions in that the lead technologist may provide problem-solving for complex instrumentation, systems, or methods.

(1) The Lead Technologist may provide training, assist in the preparation of written procedures, and may monitor quality control for new equipment or methods.

(2) The Lead Technologist may represent the section at Pathology and Laboratory Medicine Service committee meetings.

(3) The Lead Technologist position is typically filled by a technologist with national certification, and at least 2 years of comprehensive experience in a particular section or specialty area.

12.08 TESTING PERFORMED OUTSIDE PATHOLOGY AND LABORATORY MEDICINE SERVICE

a. Testing is performed outside the main facility clinical laboratory in many medical centers. This testing is classified as ancillary testing (see Ch. 10). Ancillary testing is defined as diagnostic laboratory testing or services within the jurisdiction of the medical center that are performed outside the physical facilities of the main VA medical center clinical laboratory. This includes, but is not limited to:

(1) Respiratory Therapy Laboratories performing blood gases;

(2) Nuclear Medicine Laboratories performing in vitro radioimmunoassays;

(3) Bedside;

(4) Ward and clinic testing; and

(5) Home based health care testing.

b. Ancillary Testing Committee. In medical centers where clinical laboratory testing is performed by services other than Pathology and Laboratory Medicine Service, an Ancillary Testing Committee shall be established. The committee is composed of the chiefs, or designated representatives, of all services performing laboratory testing, representatives of other services with an interest in testing procedures, or the responsibility for quality assurance and quality control. Among the committee's responsibilities are the following:

(1) Approval of tests to be performed outside the main hospital laboratory for patient, diagnostic, or monitoring purposes.

(2) Ensures that ancillary testing meets all applicable regulations and accreditation standards such as staff responsibilities, training and supervision of testing personnel, testing procedures and equipment, and the

quality management, documentation, and reliability of testing performed outside the controlled main laboratory environment.

(3) Designation of a physician in the laboratory who is responsible for the supervision of testing, infection control, and quality management for ancillary testing on a hospital-wide basis, and for the safe and accurate testing of ambulatory patients in clinics and at home.

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c. Ancillary Testing Coordinator

NOTE: D. Krienitz, and J. Little's article, "How Accelerated Regulation will affect Point-of Care Testing," Medical Laboratory Observer, Volume 23, Number 95, pp. 47-51, 1991, was used as a reference.

(1) For each ancillary testing site in the medical center, a technical consultant must be available to satisfy regulations promulgated by the Clinical Laboratory Amendments of 1988.

(2) An ancillary Testing Coordinator position has been established for VA medical centers where the technical consultant is not a laboratory physician. The Chief, Pathology and Laboratory Medicine Service, may perform this function in small VA medical centers where there are very few ancillary testing sites, or may delegate the responsibility to a qualified person (see Ch. 10) who will:

(a) Assist and advise in the evaluation of instrumentation and implementation of all testing procedures.

(b) With site supervisors and educators, plan the training and certification of all personnel performing testing outside Pathology and Laboratory Medicine Service.

(c) Review all written procedures with the ancillary testing site supervisor.

(d) Ensure that each testing area has appropriate procedures and forms for documentation.

(e) Define the clinical limits of acceptable variability for each type of test performed and provide a protocol for immediate evaluation of results and actions by testing personnel if a result is outside the specified range.

(f) Ensure that all testing procedures performed outside Pathology and Laboratory Medicine Service are periodically verified for clinically appropriate precision and accuracy, by use of external proficiency testing samples or other quality control material.

(g) Review and evaluate all quality control, instrument maintenance, and proficiency testing records.

(h) Issue reports to area coordinators on testing personnel performance on quality control and proficiency samples.

(i) Monitor compliance with all federal, state, and local governmental regulations and accreditation standards

d. Ancillary Test Site Supervisor

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(1) Each of the clinical services performing clinical laboratory testing will appoint a Site Supervisor to work with the laboratory Ancillary Testing Coordinator.

(2) The testing site supervisor will:

(a) Ensure that only personnel with appropriate training as certified by the laboratory ancillary testing coordinator and testing site supervisor perform testing.

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(b) Enroll all certified personnel in training, quality control, instrument maintenance, and proficiency testing programs.

(c) Ensure proper test result recording and reporting.

(d) Review area performance reports.

(e) Take appropriate action when poor performance is noted.

e. Ancillary Testing Personnel

(1) Testing personnel in each of the areas must have the appropriate education and training to perform the designated testing. NOTE: The ancillary testing coordinator determines if testing is of such complexity, that personnel must meet the qualification standards for medical technologist or medical technician. Exceptions are certified respiratory therapists with specific training who perform blood gas analysis and certified nuclear medicine technologists with specific training who perform radioimmunoassay testing.

(2) Testing personnel will:

(a) Document test results according to medical center policy;

(b) Perform and document quality control activities;

(c) Perform and document instrument maintenance; and

(d) Participate in proficiency testing programs.

12.09 REFERENCES

a. American Society of Clinical Pathologists, "Scope of Duties/Responsibilities for Technician and Technologist Levels of Medical Laboratory Personnel," Memorandum, April 21, 1992.

b. College of American Pathologists, Inspection Checklists, 1991.

c. Department of Health and Human Services, "Clinical Laboratory Improvement Amendments of 1988; Final Rule," Federal Register, February 28, 1992, 42 CFR Part 405, et al.

d. JCAHO, "Pathology and Clinical Laboratory Services," Accreditation Manual for Hospitals, 1992, pp. 87-102.

e. Krienitz, D., and Little J., "How Accelerated Regulation will Affect Point-of-Care Testing," Medical Laboratory Observer, Volume 23, Number 95, pp. 47-51, 1991.

f. Office of Personnel Management, "Supervisory Grade Evaluation Guide," January 1976.

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g. VHA Manual, MP-2, Part VI, Chapter 2.

h. VHA Manual, MP-2, Part VI, Chapter 10.

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i. Clinical Laboratory Management Association, "Position Description, Laboratory Managerial Functions and Duties," Memorandum, 1991.

j. VHA Supplement to MP-5, Part I, Chapter 338, Appendix 338A.

k. United States Office of Personnel Management, Handbook X-118, "Qualification Standards for Positions Under General Schedule."

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